

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	:	
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James H. HELLER et al	:	
	:	Confirmation No. 5202
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Serial No. 10/522,013	:	Art Unit: 1611
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Filed: January 21, 2005	:	Examiner: Sznaidman, M.
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For: <i>CHOLINERGIC THERAPY FOR INDIVIDUALS WITH LEARNING DISABILITIES</i>	:	Atty Docket: 000250.00029

SUPPLEMENTAL RESPONSE TO OFFICE ACTION

Commissioner of Patents
U.S. Patent and Trademark Office
Customer Service Window
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

This submission supplements the response to the non-final Office Action filed on August 12, 2008.

Applicants believe that no additional fee is required. However, if one is, the Commissioner is authorized to charge our Deposit Account No. 19-0733 appropriately.

Applicants asserted in the response filed on August 12, 2008 that the acquired cognitive impairments taught by Pratt and the developmental delays taught by Ieni are distinct from the specific learning disabilities of the present claims. 34 C.F.R. §300.8(c)(10) supports this distinction: “Specific learning disability *does not include* learning problems that are primarily the result of visual, hearing or motor disabilities, of *mental retardation*, of emotional disturbance, or of environmental, culture, or economic disadvantage.” Copy attached as Exhibit A. Developmental delays are predominantly caused by, and in some cases are synonymous with mental retardation. “Mental

retardation, which is also called developmental delay, is a condition of major clinical and social importance. The condition is characterized by a limitation of performance due to a significant impairment in measured intelligence.” Mass General for Children, copy attached as Exhibit B. Developmental Delay is the term that is used for infants or preschoolers when it is simply too early to firmly diagnose mental retardation:

In diagnosing infants or preschoolers, it is important to distinguish between mental retardation and developmental delay....In the absence of clear-cut evidence of mental retardation, it is more appropriate to use a diagnosis of developmental delay. This acknowledges a cognitive or behavioral deficit, but leaves room for it to be transitory or of ambiguous origin (Sattler, 1992). In practice, children under the age of 2 should not be given a diagnosis of mental retardation unless the deficits are relatively severe and/or the child has a condition that is highly correlated with mental retardation (e.g., Down syndrome).

“Mental Retardation: A symptom and a syndrome,” Biasini et al. Copy attached as Exhibit C. Thus developmental delay is the label applied to very young children for what otherwise would be termed mental retardation.

The Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV), the medical standard in psychiatric/psychological diagnosis, defines “learning disorders as *achievement* in individually administered standardized tests in reading mathematics, or written expression substantially *below* that expected for age, schooling and *level of intelligence*.” Clearly, this definition of learning disorders is distinct from developmental delay or mental retardation because it assesses symptoms beyond merely level of intelligence. Mental retardation, in contrast, is defined by reduced level of intelligence.

The deficits of a child with a specific learning disability is typically narrowly focused and amenable to treatment, i.e., learning compensatory strategies. Mental retardation (developmental delays), in contrast, causes a more pervasive set of

deficiencies that affect the ability to perform a broad range of tasks. Thus, it is clear that treatment of the developmental delay as taught by Leni is distinct from treatment of specific learning disabilities as recited in the subject claims.

Pratt is cited as teaching the use of donezepil to treat mild cognitive impairments. Pratt defines cognitive impairment as “an acquired deficit in one or more of memory function, problem solving, orientation and/or abstraction that impinges on an individual’s ability to function independently.” Col. 4, lines 41–45. Pratt defines mild cognitive impairments as “one or more minor symptoms of disorientation, impaired memory, impaired judgment, and/or impaired intellect.” Col. 5, lines 28–30.

Pratt is directed to treating an individual with an acquired condition, *i.e.*, something acquired later in life due to a disease or medical event. Pratt defines the cognitive impairment that he treats as “an acquired deficit.” Acquired learning problems are not specific learning disabilities. That these are distinct categories in the art is reflected, *inter alia*, in the following excerpt from Santa Monica College Disabled Student Guide, which compares *acquired* cognitive impairments, *e.g.*, from head injury from specific learning disabilities:

Comparison with Specific Learning Disabilities

On the surface, problems encountered by the person who has survived a head injury may seem like those common to students with learning disabilities. Many of the academic modifications listed for students with learning disabilities will also be appropriate for students with head injuries. Whereas similarities exist, there are important differences which have significance on effective programming.

Compared to students with learning disabilities, the student with an acquired brain injury may:

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| <ul style="list-style-type: none"> • Be more impulsive, hyperactive, distractible, verbally intrusive, and/or socially inappropriate • Have discrepancies in ability levels | <ul style="list-style-type: none"> • Be unable to process information presented through usual remedial strategies because comprehension may deteriorate as the amount and |
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<p>that are more extreme and harder to understand, such as reading comprehension at a level four years lower than spelling ability</p> <ul style="list-style-type: none">• Learn some material rapidly, since they may need only to be reacquainted with a process or concept which they knew pre-injury• Have more severe problems generalizing and integrating skills or information• Resist new learning strategies which seem too elementary (not accepting the changes caused by the injury)	<p>complexity of material increases</p> <ul style="list-style-type: none">• Require a wider variety of strategies to compensate for impaired memory and problems with word retrieval, information processing and communication• Have more pronounced difficulty with organization of thoughts, cause effect relationships, and problem solving;• Require on-going monitoring of tasks using independent thinking and judgment• Retain the pre-trauma self-concept of a student without a disability and have difficulty accepting that abilities and behaviors have changed and need to be adjusted
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Thus it is clear that the populations of individuals which Pratt and Ieni taught should be treated with cholinesterase inhibitors are distinct from that recited in the subject claims.

The information provided in this supplemental submission augments and supports the reasons that were presented in the response filed August 12. No new issues are raised in this paper.

Respectfully submitted,

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Date: August 18, 2008

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